

## REMARKS

Applicants submit this response to the Office Action dated November 22, 2005. Claim 16 is under consideration. New claims 17-19 are added to recite specific embodiments of the cell types disclosed in the application and are supported at page 35, lines 12-16. No new matter is added and entry of the amendment is respectfully requested.

Claim 16 was rejected under 35 U.S.C. § 101 for allegedly lacking a specific and substantial asserted utility of a well established utility. Reconsideration and withdrawal of this rejection are respectfully requested.

According to the Examiner, kinases are known in the art to have diverse biological functions and substrate specificities. The Examiner cites a publication related to protein function prediction, specifically, Whisstock *et al.*, Quar. Rev. Biophys. 36:307-340, 2003. Applicants have reviewed the publication and submit that it is not on point in relation to the method claimed in claim 16, and new claims 17-19, because the claims recite over-expression of a hPNQALRE gene product. Example 1 in the patent application relates to over-expression of mRNA in cancer cells. The structure, function, and activity of the protein are not recited in the claimed methods, so Whisstock is not applicable to the method of detecting a cancer cell using a polynucleotide as recited in the claims.

The specification teaches that the hPNQALRE gene of the invention is expressed at a higher level in cancer cell lines, particularly a lung cancer cell line, an epithelial cancer cell line, and a colon cancer cell line. Claims 16-19 have utility as providing methods for determining if a cell is neoplastic. The use of polynucleotide diagnostics for distinguishing normal and neoplastic tissue is well known in the art, and the present application provides an additional polynucleotide, based on hPNQALRE, for performing such analyses.

Exemplary of many issued patents are the following: U.S. Patent No. 6,210,883, which discloses and claims a method for detecting lung cancer using polynucleotide probes; U.S. Patent No. 6,004,756, which discloses and claims a method for detecting breast cancer by mRNA expression; and U.S. Patent No. 5,882,864, which discloses

and claims detecting RNA in prostate cancer cells. The claimed method clearly meets the utility standard, and withdrawal of the rejection on this ground is requested.

Claim 16 was rejected under 35 U.S.C. § 112, first paragraph, as one of skill in the art allegedly would not know how to use the claimed invention. Reconsideration and withdrawal of this rejection are respectfully requested.

The claimed method is directed towards using a polynucleotide for diagnosing or prognosing neoplasia. Without acquiescing to the ground of rejection, applicants submit that claim 16, and new claims 17-19, are not subject to this ground of rejection because they recite "determining if a cell is neoplastic." This is clearly taught in the application and one of skill would know how to use the invention, based on well-known methods of using polynucleotide markers to distinguish normal and neoplastic cells. In view of the present claim language, applicants submit that the Molina *et al.* (Tumour Biol. 26:281-293, 2005) reference is not on point.

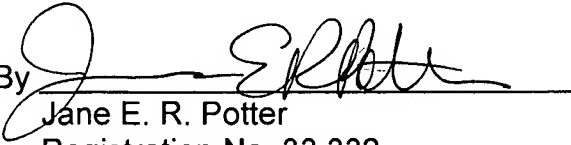
Applicants refer again to the issued patents discussed above, which claim methods of identifying tumor cells using polynucleotide hybridization, including detection of altered levels of tumor cell mRNA. Applicants submit that one of skill would clearly know how to use the claimed method. Withdrawal of the rejection on this ground is requested.

Commissioner is hereby authorized to charge the required fees of \$1,020, to Deposit Account No. 04-0258. If additional fees are believed necessary, the Commissioner is further authorized to charge any deficiency or credit any overpayment to Deposit Account No. 04-0258.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

If questions remain regarding this application, the Examiner is invited to contact the undersigned at (206) 628-7650.

Respectfully submitted,  
Christoph Reinhard  
DAVIS WRIGHT TREMAINE LLP

By   
Jane E. R. Potter  
Registration No. 33,332

2600 Century Square  
1501 Fourth Avenue  
Seattle, WA 98101-1688  
Phone: (206) 628-7650  
Facsimile: (206) 628-7699